THIS OPINION WAS NOT WRITTEN FOR PUBLICATION

The opinion in support of the decision being entered today (1) was not written for publication in a law journal and (2) is not binding precedent of the Board.

Paper No. 44

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

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Ex parte A. RICHARD CHAMBERLIN, RICHARD J. BRIDGES, CARL W. COTMAN and MARK S. STANLEY

_____

Appeal No. 96-0009
Application 08/104,417[1]

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ON BRIEF

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Before SOFOCLEOUS, KIMLIN, and OWENS, *Administrative Patent Judges.*

OWENS, *Administrative Patent Judge.*

DECISION ON APPEAL

This is an appeal from the examiner's final rejection of claims 1-4 and 22-24, which are all of the claims remaining in

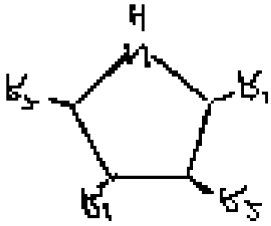
[1] Application for patent filed August 9, 1993. According to appellants, the application is a continuation of Application 07/427,235, filed October 25, 1989, abandoned.

the application.

THE INVENTION

Appellants claim a method of inhibiting the transport of a neurotransmitter away from a synapse by contacting the synapse with a recited compound wherein the compound is capable of inhibiting the uptake of L-glutamate into synaptosomes and the neurotransmitter is capable of binding a transporter which binds L-glutamate. Claim 1 is illustrative and reads as follows:

1. A method of inhibiting the transport of a neurotransmitter away from a synapse comprising contacting said synapse with a compound selected from the group consisting of compounds having the structure:



wherein R^1 = CO_2R^3; $P(OR^3)_2$; $P(OH)(OR^3)$; SO_3R^3; or $CONHR^3$ in any combination;
R^2 = OR^3, NR^3_2, alkyl, or H; and
R^3 = alkyl, substituted alkyl, or H,
wherein the compounds are capable in inhibiting the uptake of L-glutamate into synaptosomes, and wherein said

neurotransmitter is capable of binding a transporter which binds L-glutamate.

THE REJECTION

Claims 1-4 and 22-24 stand rejected under 35 U.S.C. § 101 on the ground that the claimed invention lacks utility.

OPINION

We have carefully considered all of the arguments advanced by appellants and the examiner and agree with appellants that the aforementioned rejection is not well founded. This rejection therefore will be reversed.

In parent Application 07/427,235, the examiner rejected claims 1-4 and 22-24 under both 35 U.S.C. § 101 (lack of utility) and 35 U.S.C. § 112, first paragraph (nonenablement) (paper no. 20). In the present application, the only rejection is under 35 U.S.C. § 101 (lack of utility). The examiner, however, presents arguments directed toward lack of enablement (answer, pages 3, 6 and 7) and appellants argue that the claimed invention is enabled (brief, pages 9-14). For this reason and because absence of utility can be the basis of a rejection under both 35 U.S.C. § 101 and 35 U.S.C.

§ 112, first paragraph, *see In re Brana*, 51 F.3d 1560, 1564 n. 12, 34 USPQ2d 1436, 1439 n.12 (Fed. Cir. 1995); *In re Jolles*, 628 F.2d 1322, 1326 n.10, 206 USPQ 885, 889 n.11 (CCPA 1980); *In re Fouche*, 439 F.2d 1237, 1243, 169 USPQ 429, 434 (CCPA 1971), we address both the issues of utility and enablement.

Appellants point out that the claimed invention is directed toward a method for inhibiting the L-glutamate neurotransport system and not toward a method for treating disorders of central nervous systems in humans, and argue that in their method, as stated in their specification (page 5, lines 6-14), specific inhibitors of L-glutamate uptake provide useful probes for evaluating the role of the transport system in neurotransmission (brief, pages 15 and 18). As evidence that the claimed invention has the asserted utility, appellants rely upon their specification, the second declaration of Dr. Richard Bridges, filed on March 14, 1994, and an advertisement newsletter by the British company Tocris Neuramin.[2]

[2] The Tocris Neuramin advertisement newsletter states that L-trans-pyrrolidine-2,4-dicarboxylic acid inhibits L-glutamate uptake into synaptosomes, but provides no supporting data.

Appellants argue (brief, page 15) that their specification (page 4, lines 11-14; page 13, lines 6-29; page 15, line 2 - page 16, line 14) shows that the recited inhibitors are selective to the transport system and do not bind glutamate receptors, and that the claimed method is useful for studying the neurotransport system. Appellants further argue (brief, page 18) that the specification (page 3, lines 21-31; Figure 3 and Examples II-IV) shows the specificity and effectiveness of the recited compounds in preventing the uptake of L-glutamate away from nerve synapses as indicated by a synaptosomal uptake assay which is well-established in the art.

The second declaration of Dr. Bridges (paragraphs 4 and 5) presents in vivo tests on laboratory rats and in vitro tests which show that L-trans-pyrrolidine-2,4-dicarboxylate inhibits the transport of L-glutamate from nerve synapses.

Regarding enablement, appellants also point out that their claimed invention is directed toward the application of inhibitor compounds to a nerve synapse to inhibit the uptake of the neurotransmitter away from the synapse, and is not directed toward the treatment of any particular disease

(brief, pages 11-12). Appellants argue (brief, page 10) that their specification (page 12, line 12 to page 15, line 1; Examples II and III) shows that four compounds within the scope of appellants' claims produce some degree of inhibition as indicated by the synaptosomal assay in the specification. Appellants also argue (brief, page 10) that the first declaration of Dr. Bridges, filed on October 8, 1992, provides evidence of the effectiveness of L-trans-pyrrolidine-4-sulfono-2-carboxylate for inhibiting D-aspartate uptake into synaptosomes. The test results for these five inhibitors, appellants argue, are sufficient to establish enablement of appellants' claimed invention (brief, page 10).

Regarding utility, a predecessor of our reviewing court stated in *In re Langer*, 503 F.2d 1380, 1391, 183 USPQ 288, 297 (CCPA 1974):

> [A] specification which contains a disclosure of utility which corresponds in scope to the subject matter sought to be patented *must* be taken as sufficient to satisfy the utility requirement of § 101 for the entire claimed subject matter *unless* there is reason for one skilled in the art to question the objective truth of the statement of utility or its scope.

As for enablement, the court similarly stated in *In re*

Marzocchi, 439 F.2d 220, 223, 169 USPQ 367, 369 (CCPA 1971):

> [A] specification disclosure which contains a teaching of the manner and process of making and using the invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented *must* be taken as in compliance with the enabling requirement of the first paragraph of §112 *unless* there is reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support.

When making a rejection under 35 U.S.C. § 101, an examiner must do more than merely question operability. *In re Gaubert*, 524 F.2d 1222, 1224-25, 187 USPQ 664, 666 (CCPA 1975). The examiner "must set forth *factual reasons* which would lead one skilled in the art to question the objective truth of the statement of operability" (*id.*).

In the present case, the examiner states that appellants claim a mechanism of chemical reactions within the body which are speculative and that appellants' method for inhibiting transport of a neurotransmitter away from a synapse is on its face unbelievable (answer, page 4), but the examiner provides no factual basis for these assertions.

The examiner argues that appellants have not established

a utility or provided an enabling disclosure for a method for treating a medical disorder (answer, pages 3-7). As pointed out by appellants as discussed above, appellants are claiming a method for inhibiting the transport of a neurotransmitter away from a synapse, which is useful for studying the neurotransport system. Appellants have set forth the evidence discussed above which appears to indicate that appellants' claimed method has the asserted utility and that their method is enabled by their specification. The examiner has provided no evidence to the contrary.

Because appellants have provided what appears to be credible evidence of utility and the examiner has not set forth evidence in support of his assertion of lack of utility, the examiner's rejection is not sustained.

DECISION

The rejection of claims 1-4 and 22-24 under 35 U.S.C. § 101 on the ground that the claimed invention lacks utility is reversed.

REVERSED

MICHAEL SOFOCLEOUS Administrative Patent Judge	)	
EDWARD C. KIMLIN Administrative Patent Judge	)	BOARD OF PATENT APPEALS AND INTERFERENCES
TERRY J. OWENS Administrative Patent Judge	)	

TJO/pgg

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